# AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE

**Administrative Office**
1209 Montgomery Highway
Birmingham, Alabama 35216-2809
Tel 205/978-5000 • Fax 205/978-5005
Email asrm@asrm org • Web Site http //www asrm org

**J. Benjamin Younger Office of Public Affairs**
409 12th Street SW, Suite 203
Washington, DC 20024-2188
Tel 202/863-4985 • Fax 202/484-4039





November 17, 2005

Andrew C. von Eschenbach, MD
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Parklawn Building, Room 14-71
Rockville, MD 20857

Dear Acting Commissioner von Eschenbach:

On behalf of the American Society for Reproductive Medicine (ASRM), I am writing to comment on a Citizen Petition currently pending before the Food and Drug Administration (FDA) on the issue of bioidentical hormone replacement therapies. Founded in 1944, ASRM has almost 8,500 members who are devoted to advancing knowledge and expertise in reproductive medicine and biology.

ASRM members recognize the appropriate role of hormone therapy, and the importance of sitting down with our patients to discuss the best course of action for them, based on their menopausal symptoms, medical history, and family history. This discussion is a challenging one, since many women have been confused by the results of the Women's Health Initiative. We fear that the misleading and unsubstantiated claims about the superiority of bioidentical hormones made by some compounding pharmacies are only adding to the confusion.

At the urging of the Congress, the FDA initiated and implemented the *Menopausal Hormone Therapy Information Campaign.* Our organization was pleased to have served as an organizational partner with FDA on that campaign. As a complement to this effort, ASRM believes that FDA must take steps to provide women with guidance about bioidentical hormones, and to prevent any illegal promotional activities by certain compounding pharmacies.

ASRM is also concerned about potential safety issues surrounding the use of some compounded bioidentical hormone

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therapy products -- particularly the inclusion of estriol. This estrogen does not appear in any FDA-approved drug, and thus may carry unknown health risks. Furthermore, ASRM is troubled by some compounding pharmacies' practice of determining the appropriate dose of hormones based on a salivary test. Salivary testing may not provide an accurate measurement of an individual's hormone levels. Only a blood sample is an accurate measurement of these levels. Further, it should be noted that hormone therapy does not belong to a class of drugs with an indication for individualized dosing.

ASRM agrees with The American College of Obstetricians and Gynecologists' (ACOG) recent Committee Opinion on *Compounded Bioidentical Hormones* that "Most compounded products have not undergone rigorous clinical testing for safety or efficacy, and issues regarding purity, potency, and quality are a concern. Compounded hormone products have the same safety issues as those associated with hormone therapy agents that are approved by the U.S. Food and Drug Administration and may have additional risks intrinsic to compounding. There is no scientific evidence to support claims of increased efficacy or safety for individualized estrogen or progesterone regimens."

ASRM believes that FDA must do its job to protect women's health by communicating accurate information about bioidentical hormones to women and health professionals, and if necessary, cracking down on compounding pharmacies that are found to be engaged in illegal activities.

We urge the agency to assert its leadership on this important women's health issue, and request that this letter be included in Docket Number 2005P-0411. ASRM is most interested in learning what steps the FDA has taken or intends to take on this matter.

Sincerely,

Robert W. Rebar, MD

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Robert W. Rebar, MD
Executive Director

Cc: Robert J. Temple, MD
Director, Office of Medical Policy

Scott Gottlieb, MD
Deputy Commissioner for Medical and Scientific Affairs